

**EXCEDRIN PM TRIPLE ACTION CAPLETS AND EXCEDRIN EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin (nsaid), caffeine, and diphenhydramine citrate**  
**Haleon US Holdings LLC**

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***Drug Facts***

**Excedrin PM Headache**

***Active ingredients (in each caplet)***

Acetaminophen 250 mg

Aspirin 250 mg (NSAID\*)

Diphenhydramine citrate 38 mg

\*nonsteroidal anti-inflammatory drug

***Purposes***

Pain reliever

Pain reliever

Nighttime sleep-aid

***Uses***

- for the temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

***Warnings***

**Reye's syndrome:**Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:**Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Allergy alert:**Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)

- shock

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 2 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

### **Do not use**

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age

### **Ask a doctor before use if**

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma
- you have glaucoma
- you have a breathing problem such as emphysema or chronic bronchitis
- you have trouble urinating due to an enlarged prostate gland

### **Ask a doctor or pharmacist before use if you are**

taking

- a prescription drug for:
  - diabetes
  - gout
  - arthritis
- any other drug, or are under a doctor's care for any serious condition
- any product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer
- sedatives or tranquilizers

**When using this product**

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- pain gets worse or last for more than 10 days
- painful area is red or swollen
- ringing in the ears or a loss of hearing occurs
- any new symptoms occur

These could be signs of a serious condition

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

***Directions***

- **do not use more than directed**
- do not use in children under 12 years of age
- adults and children 12 years of age and over: take 2 caplets at bedtime, with a full glass of water
- do not take more than 2 caplets in 24 hours, unless directed by a doctor

***Other information***

- store at 20°-25°C (68°-77°F).
- close cap tightly after use.
- read all product information before using. Keep this box for important information.

***Inactive ingredients***

benzoic acid, calcium carbonate, FD&C blue#1 aluminum lake, hydroxypropyl cellulose low substituted, hypromellose, magnesium stearate, maltodextrin, medium-chain triglycerides, polydextrose, polysorbate 80, povidone, pregelatinized corn starch, silicified microcrystalline cellulose, stearic acid, talc, titanium dioxide, yellow iron oxide, zinc stearate

### ***Questions or comments?***

**1-800-452-0051**

### **Excedrin Extra Strength**

[Enter Generic Section here]

### ***Active ingredients (in each caplet)***

Acetaminophen 250 mg

Aspirin 250 mg (NSAID\*)

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

### ***Purposes***

Pain reliever

Pain reliever

Pain reliever aid

### ***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - toothache
  - premenstrual & menstrual cramps

### ***Warnings***

**Reye's syndrome:**Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:**Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat.

### **Do not use**

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

### **Ask a doctor before use if**

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

### **Ask a doctor or pharmacist before use if you are taking**

- a prescription drug for diabetes, gout, or arthritis

- any other drug, or are under a doctor's care for any serious condition

### **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- painful area is red or swollen
- pain gets worse or last for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms occur

These could be signs of a serious condition

### **If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

### **Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### ***Directions***

- **do not use more than directed**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

### ***Other information***

- store at 20°-25°C (68°-77°F)
- close cap tightly after use
- read all product information before using. Keep this box for important information.

### ***Inactive ingredients***

benzoic acid, carnauba wax, FD&C blue #1, hydroxypropylcellulose, hypromellose, light mineral oil, microcrystalline cellulose, polysorbate 20, povidone, propylene glycol, simethicone emulsion, sorbitan monolaurate, stearic acid, titanium dioxide

**Questions or comments?**

**1-800-452-0051**

**Principal Display Panel (Excedrin PM Headache)**

**DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME. USE PRODUCTS AS DIRECTED.**

**NDC 0067-2056-24**

**EXCEDRIN®**

**PM HEADACHE**

**Acetaminophen, Aspirin (NSAID) and Diphenhydramine Citrate  
Pain Reliever/Nighttime Sleep-Aid**

**Triple Action Formula**

**Caffeine-Free**

**Non-Habit Forming**

**24 CAPLETS**

**TAMPER-EVIDENT BOTTLE**

**DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH “SEALED for YOUR PROTECTION” IS BROKEN OR MISSING**

Distributed by: **GSK Consumer Healthcare**

Warren, NJ 07059

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**Visit us at [www.excedrin.com](http://www.excedrin.com)**

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*Triple Action Formula*

NDC 0067-2058-24

# EXCEDRIN®

## PM HEADACHE

*Acetaminophen, Aspirin (NSAID)  
and Diphenhydramine Citrate*

*Pain Reliever / Nighttime Sleep-Aid*

*Caffeine-Free  
Non-Habit Forming*

**24  
CAPLETS**



**Principal Display Panel (Excedrin Extra Strength)**

**NDC 0067-2000-91**

**EXCEDRIN®**

**EXTRA STRENGTH**

**Acetaminophen, Aspirin (NSAID) and Caffeine**

**Pain Reliever / Pain Reliever Aid**

**100 CAPLETS**

**TAMPER-EVIDENT BOTTLE**

**DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH "SEALED for YOUR PROTECTION" IS BROKEN OR MISSING**

Distributed by: **GSK Consumer Healthcare**, Warren, NJ 07059

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**Visit us at [www.excedrin.com](http://www.excedrin.com)**

**DO NOT TAKE BOTH PRODUCTS AT THE SAME TIME. USE PRODUCTS AS DIRECTED.**

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NDC 0067-2000-91

# EXCEDRIN<sup>®</sup>

## EXTRA STRENGTH

Acetaminophen, Aspirin (NSAID) and Caffeine  
Pain Reliever/Pain Reliever Aid

100  
CAPLETS



### EXCEDRIN PM TRIPLE ACTION CAPLETS AND EXCEDRIN EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin (nsaid), caffeine, and diphenhydramine citrate kit

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0067-8148
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#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-8148-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	05/01/2018	

#### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	24
Part 2	1 BOTTLE	100

#### Part 1 of 2

### EXCEDRIN PM TRIPLE ACTION CAPLETS

acetaminophen, aspirin (nsaid) and diphenhydramine citrate tablet, coated

## Product Information

Item Code (Source) NDC:0067-2056

Route of Administration ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
<b>DIPHENHYDRAMINE CITRATE</b> (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 2165RE0K14)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>ZINC STEARATE</b> (UNII: H92E6QA4FV)	

## Product Characteristics

<b>Color</b>	blue (light blue)	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	EXPM
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-2056-24	1 in 1 CARTON		
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/24/2014	

## Part 2 of 2

### EXCEDRIN EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin (nsaid), and caffeine tablet, film coated

## Product Information

Item Code (Source)	NDC:0067-2000
Route of Administration	ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>DIMETHICONE, UNSPECIFIED</b> (UNII: 92RU3N3Y1O)	
<b>SORBITAN MONOLAURATE</b> (UNII: 6W9PS8B71J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	white (White)	Score	no score
Shape	CAPSULE (Capsule-Shaped Tablet)	Size	18mm

<b>Flavor</b>		<b>Imprint Code</b>	E	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-2000-91	1 in 1 CARTON		
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	09/27/2006		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	05/01/2018		

**Labeler** - Haleon US Holdings LLC (079944263)

Revised: 2/2026

Haleon US Holdings LLC